

SunSprout Enterprises, Inc. December 9, 1999

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Dockets Management Branch (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Dockets 99D-4488, 99D-4489

To Whom It May Concern:

First, we wish to go on record in appreciation for the involvement of the FDA in intervening for the production of safe sprouts. The nutrient density of sprouts brings unsurpassed value to the American public in their search for healthy eating, and the assurance of a safe product is of primary importance to producers.

However, the Guidance document referenced above brings certain hardships and risks to our industry we feel could be alleviated with alternative solutions. Following are written comments we wish to have submitted for consideration in preparation of potential document revisions regarding guidance for the sprouting industry.

- Laboratory testing of each individual batch or production lot of sprouts:
Because of the costs associated with testing product, we at SunSprout will need to eliminate many of the specialty products we currently carry. As a relatively small producer (~\$250,000 annually), any quantity sprout such as gourmet, spicy, sunflower, daikon, etc. that does not meet a minimum sales dollar will not support the expense of laboratory testing. One concern is elimination of these products by our facility will send our customers to other markets which could supply all their sprout needs. In the end the effects of diminished market share would leave the control of the sprouting industry in the hands of few and subjecting the supply to huge shipment areas, greatly impacting freshness and safety of the product.

Additionally, the literature does not associate ALL sprouts with the indicated pathogens, and some are typically cooked prior to consumption, diminishing the need for testing. We therefore ask exceptions to the "*all" statement.

- Disinfection treatments:
The blanket use of 20,000 parts per million of Ca hypochlorite does not address the differences in the water source for different sprouts producers. For instance, the properties in our municipal water used here at SunSprout is considerably different

Sprout yourself healthy!

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than well-water used by other producers, giving different results with the standard use of 20K.

Of additional concern, we feel this standard quantity which required EPA exemption, will have a detrimental long-term effect in our production plants related to the reduction of background (all?) flora.

Prior to the FDA guidelines, we disinfected our seed using an ORP (Oxidation reduction potential) meter which validated the capacity of the sanitizer to destroy the present pathogens. We are in the process of attempting to acquire validation of this method through AOAC, and ask the door be left open for methods other than the 20K.

- Sample collection:

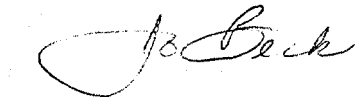
In meeting with the independent laboratory used by SunSprout, we collaboratively felt the recommended process of holding the liter collection container along with the lid in *one hand* is not feasible and therefore asked the process of this to be reviewed.

- Presumptive Positives:

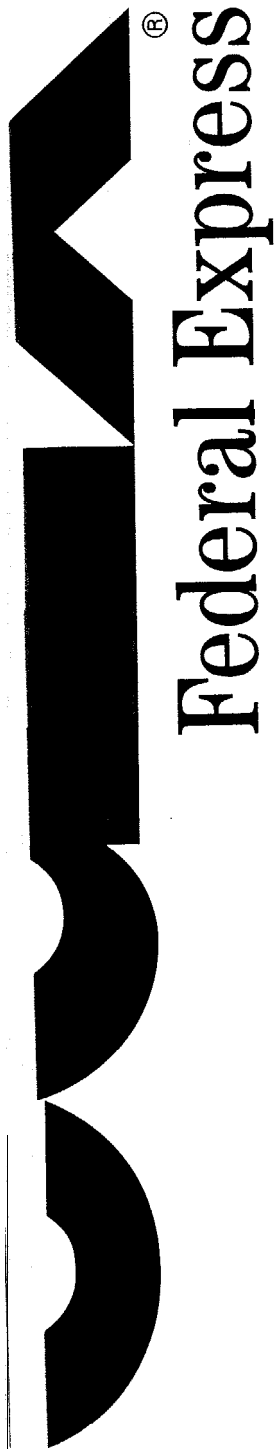
Common rates of presumptive positive test results in the lab industry creates several crises in the sprouting industry. The major logistical issues affected are related to concurrent product and facility environs, plus the erosion of customer confidence unnecessarily. Our small plant would be literally shut down based on a false presumptive positive. We urge the **continued search** for standardized **preproduction** testing of seed that would result in ,a safe product.

Again, we appreciate the work on the part of FDA, and ask the above comments be afforded consideration for the final documents.

Sincerely,

A handwritten signature in cursive script, appearing to read "Jo Beck".

Jo Beck, Owner



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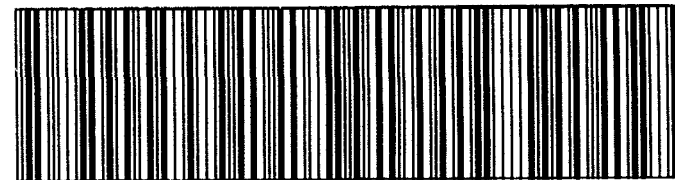
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